

ON ONE HAND AND THE OTHER: HOW COMPETING GOALS IMPERIL THE AFFORDABLE CARE ACT'S SUCCESS

Jean Wright Veilleux*

INTRODUCTION

Presidents Truman, Nixon, Clinton, and George W. Bush all recognized a need for health care reform to increase the number of Americans with health insurance. They all tried and failed to pass comprehensive health care reform.¹ Their failures underscore the difficulty of the task, both politically and practically. With the passage of the Patient Protection and Affordable Care Act (ACA),² President Obama achieved what other presidents could not. However, passage of the law may not ultimately prove to be the difficult part.

As the Department of Health and Human Services (HHS) and, in particular, Centers for Medicare and Medicaid Services (CMS) face the enormous task of putting flesh on the 900 plus pages of bones in the ACA, they must confront the contradictions and limitations of the ACA's provisions. The ACA has three overarching goals: enhancing quality of care, improving Americans' health, and reducing per capita health care costs.³ The ACA employs two major cost-containment strategies that are both central to the success of the ACA and in direct conflict with one another: (1) promoting physician-hospital partnerships or other alignment strategies to promote improved care and greater efficiency of care delivery; and (2) controlling fraud and abuse in government-funded health care programs.

Both strategies hope to keep burgeoning health care costs in check, and the alignment strategies further seek to improve the quality of care for patients. Whether the ACA will achieve its ambitious goals is beyond the scope of this Article. I simply argue that the two strategies conflict in

* J.D. 1985, George Washington University; LL.M. 1991, George Washington University. The author is Assistant Professor of Law at the Charlotte School of Law. Prior to joining the faculty, Prof. Veilleux had a private practice specializing in health care fraud and abuse. She also served as General Counsel to Presbyterian Healthcare in Charlotte, North Carolina from 1997 to 2003.

1. David M. Herszenhorn, *A Deep Divide Separated by Plenty of Common Ground*, N.Y. TIMES, Jan. 31, 2010, <http://prescriptions.blogs.nytimes.com/2010/01/31/a-deep-divide-separated-by-plenty-of-common-ground>.

2. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 3022, 10307, 124 Stat. 119 (2010) (codified as amended at 42 U.S.C. §1395jii).

3. Donald M. Berwick et al., *The Triple Aim: Care, Health, and Cost*, 27 HEALTH AFF. 759, 760 (May 2008), available at <http://content.healthaffairs.org/content/27/3/759.full.pdf>.

fundamental ways at present due to the content of the fraud and abuse laws and the ways they are interpreted and enforced by the agencies responsible for them. Significant changes will be required in the fraud and abuse laws to attempt to reconcile these conflicts and improve the chances that the ACA will not go the way of the reform efforts before it.

I. THE ACA'S FOCUS ON COST CONTAINMENT

A. *The Need for Cost Containment*

Americans spend tremendous amounts of money on health care, and yet, at least by many measures, have relatively little to show for it. In 2013, national-health spending is projected to be 17.8% of the United States' gross domestic product.⁴ "Health spending per capita in the United States is much higher than in other countries—at least \$2,535, or 51%, higher than Norway, the next largest per capita spender."⁵ Furthermore, the United States spends nearly double the average \$3,923 for 15 countries⁶ that rank in the top three-fifths of per capita national income and aggregate national income.⁶ In addition, spending in the United States is increasing much more quickly than almost any other developed country.⁷ Consequently, "[o]ver the last thirty years the difference between the United States' spending and comparable countries has widened."⁸

And yet all this spending has not resulted in exemplary health for Americans. The Kaiser Family Foundation noted in a 2011 report that "[d]espite . . . [its] relatively high level of spending, the U.S. does not appear to provide substantially greater health resources to its citizens, or achieve substantially better health benchmarks, compared to other developed countries."⁹ Dr. David Pate, a physician and the CEO of a large

4. CTRS. FOR. MEDICARE & MEDICAID SERVS., OFFICE OF THE ACTUARY, NATIONAL HEALTH EXPENDITURES PROJECTIONS 2011-2021, Tbl. 1, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2011PDF.pdf> (last visited Dec. 1, 2013).

5. KAISER FAMILY FOUND., *Health Care Spending in the United States and Selected OECD Countries*, Ex. 1 (Apr. 2011), <http://www.kff.org/insurance/snapshot/OECD042111.cfm>.

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.* (citing Gerard F. Anderson et al., *Health Care Spending and Use of Information Technology in OECD Countries*, 25 HEALTH AFF. 819, 819–831 (2006), available at <http://content.healthaffairs.org/content/25/3/819.full.html>); GERARD F. ANDERSON & DAVID A. SQUIRES, THE COMMONWEALTH FUND, MEASURING THE U.S. HEALTH CARE SYSTEM: A CROSS-NATIONAL COMPARISON (June 2010), available at <http://www.commonwealthfund.org/Content/Publications/Issue-Briefs/2010/Jun/Measuring-the-US-Health-Care.aspx>; KAREN DAVIS ET. AL., THE COMMONWEALTH FUND, MIRROR, MIRROR ON THE WALL: HOW THE PERFORMANCE OF THE U.S.

health care system, wrote recently, “Health care is not safe enough, it is not ‘high reliability’ in terms of outcomes, there is too much irrational variation in care, it is too fragmented, it is often inconvenient to access, and it is increasingly unaffordable, even for those with health care insurance.”¹⁰

B. The Problem with the Fee-For-Service Payment System

Many health care policy scholars make the case that the current fee-for-service payment system is a major factor in the problems plaguing the American health care system.¹¹ They argue that fee-for-service payments discourage cooperation between hospitals and physicians and create unnecessarily high health care costs.¹² When physicians and hospitals are paid for services on a “piecemeal” basis, they have every incentive to provide as many services as possible, even if some of those might not be medically necessary or even medically appropriate.¹³ The Institute of Medicine released a major report in September 2012 arguing, among other things, that, “[s]everal common payment systems can promote greater use of care. When each service generates additional revenue, there is a strong economic incentive for clinicians and health care organizations to provide more interventions and diagnostic procedures, treat with greater intensity, and care for more patients.”¹⁴

HEALTH CARE SYSTEM COMPARES INTERNATIONALLY 2010 UPDATE, (June 2010), *available at* <http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2010/Jun/Mirror-Mirror-Update.aspx>; GERARD F. ANDERSON AND PATRICIA MARKOVICH, THE COMMONWEALTH FUND, MULTINATIONAL COMPARISONS OF HEALTH SYSTEMS DATA, 2009 (Nov. 2009), *available at* <http://www.commonwealthfund.org/Content/Publications/Chartbooks/2009/Multinational-Comparisons-of-Health-Systems-Data-2009.aspx>.

10. David C. Pate, *Hospital-Physician Relations in a Post-Health Care Reform Environment*, 33 J. OF LEGAL MED. 7, 11 (2012) (citing David A. Hyman, *The Poor State of Health Care Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution?*, 90 CORNELL L. REV. 893, 900–08 (2005)).

11. See RESEARCH TRIANGLE INST., PAY FOR PERFORMANCE IN HEALTH CARE: METHODS AND APPROACHES 2, 99, 341 (Jerry Cromwell et al. eds., 2011) (listing problems of the fee-for-service system).

12. See *id.* at 7–8, 141, 341 (describing specific problems of the fee-for-service system including inefficient practices between providers and practitioners and the lack of incentives for improving quality and reducing costs).

13. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-355, MEDICARE: IMPLEMENTATION OF FINANCIAL INCENTIVE PROGRAMS UNDER FEDERAL FRAUD AND ABUSE LAWS 1–2 (2012) [hereinafter MEDICARE] (citing a 2007 study estimating that up to two percent of all cancers in the United States may be attributable to radiation from CT scans); see generally ATUL GAWANDE, COMPLICATIONS: A SURGEON'S NOTES ON AN IMPERFECT SCIENCE (Picador ed., 2003).

14. THE INST. OF MED., BEST CARE AT LOWER COST: THE PATH TO CONTINUOUSLY LEARNING HEALTH CARE IN AMERICA 230 (2013) [hereinafter INST. OF MED. REPORT], *available at* http://www.nap.edu/catalog.php?record_id=13444.

In addition to the incentive for more services, the current fee-for-service approach also creates incentives for hospitals and physicians to compete instead of working together to achieve efficiency and quality goals.¹⁵ Hospitals are currently reimbursed primarily on the basis of “diagnosis-related group” (DRG) payments. DRG payments are single charges for all inpatient hospital costs related to a single hospital visit.¹⁶ Physicians, by contrast, are reimbursed under a physician fee schedule that pays them for each patient encounter.¹⁷ Hospitals have incentives to decrease costs for hospital stays, while physicians have incentives to increase services associated with each stay to maximize their revenue.¹⁸

Dr. Atul Gawande conducted a study of a single Texas town with significantly higher costs than other towns in its region.¹⁹ He concluded that physicians’ competition with hospitals for a greater share of the health care dollar contributes significantly to the overall escalation of health care costs.²⁰ Dr. Gawande writes:

When you look across the spectrum from Grand Junction to McAllen[, Texas]—and the almost threefold difference in the costs of care—you come to realize that we are witnessing a battle for the soul of American medicine. Somewhere in the United States at this moment, a patient with chest pain, or a tumor, or a cough is seeing a doctor. And the damning question we have to ask is whether the doctor is set up to meet the needs of the patient, first and foremost, or to maximize revenue. There is no insurance system that will make the two aims match perfectly. But having a system that does so much to misalign them has proved disastrous. As economists have often pointed out, we pay doctors for quantity, not quality. As they point out less often, we also pay them as individuals, rather than as members of a team working together for their patients. Both practices have made for serious problems.²¹

15. Julie E. Kass & John S. Linehan, *Fostering Healthcare Reform through a Bifurcated Model of Fraud and Abuse Regulation*, 5 J. HEALTH & LIFE SCI. L. 75, 79 (2012).

16. 42 U.S.C. § 1395ww (2012).

17. 42 U.S.C. § 1395w-4.

18. Barry S. Coller, *Realigning Incentives to Achieve Health Care Reform*, 306 J. AM. MED. ASS’N 204, 204 (2011).

19. See Atul Gawande, *The Cost Conundrum: What a Texas Town Can Teach Us About Health Care*, NEW YORKER, June 1, 2009, at 4, available at http://www.newyorker.com/reporting/2009/06/01/090601fa_fact_gawande#ixzz2MluABATr (explaining that the lack of oversight of healthcare costs causes an increase in these costs).

20. *Id.*

21. *Id.* at 14.

Hospitals are not immune to the profit motive either. The current payment system includes higher payments for certain services performed in hospitals than when those same services are performed in physicians' offices.²² One example of such services is chemotherapy administration. Hospitals take advantage of the so-called "site of service differential" by buying physician practices and then employing the physicians to provide chemotherapy in what becomes a "hospital-based" practice.²³ The Urban Institute's Health Policy Center reports that hospitals receive about 80% more than independent doctors for many routine services under the Medicare payment schedule.²⁴ A recent investigation by two North Carolina newspapers found that free-standing physician offices in the Charlotte, North Carolina area charge \$200.35 for an echocardiogram, while hospital outpatient facilities charge \$446.06 for the same test.²⁵

One approach to cutting costs might be to simply cut physician or hospital reimbursement. However, these cuts have proven very difficult politically.²⁶ Congress passed a complicated scheme to cut physician payments in 1989 but has postponed implementation of the cuts required by the program every year since 2003.²⁷ The most recent postponement of the cuts occurred in January 2013 when Congress passed, and President Obama signed, a law keeping Medicare physician fees level through the end of 2013 and cutting hospital payments somewhat to help offset the cost.²⁸

Any resolution of the physician payment issue is likely to involve a deal giving physicians small or no cuts in fees for a few years while HHS works on creative alternatives to the traditional fee-for-service payment model. In 2012, both the House and Senate held hearings to explore possible alternatives.²⁹ Physician groups supported approaches that would keep the fee schedule at the current rate for primary care and decrease it slightly for specialty care for the next five years, during which time the Medicare program would continue experimenting with ideas such as the pay-for-performance model and Accountable Care Organizations (ACOs).³⁰

22. See *infra* notes 24–25 and accompanying text.

23. Ames Alexander et al., *As Doctors Flock to Hospitals, Bills Spike for Patients*, CHARLOTTE OBSERVER, Dec. 16, 2012, at 8A, <http://www.charlotteobserver.com/2012/12/17/3728676/as-doctors-flock-to-hospitals.html>.

24. *Id.*

25. *Id.*

26. Alexander et al., *supra* note 23.

27. *Medicare*, N.Y. TIMES, Jan. 2, 2013, <http://topics.nytimes.com/top/news/health/diseasesconditionsandhealthtopics/medicare/index.html>.

28. American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 601, 126 Stat. 2345 (2013).

29. *Medicare Payments to Physicians (Updated)*, *Health Policy Briefs*, HEALTH AFFS. (Jan. 10, 2013), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=83.

30. Medicare Physician Payment Innovation Act of 2013, H.R. 574, 113th Cong. (2013).

Even if Congress were to muster the political will to significantly cut physician reimbursement schedules, past experience shows that the traditional fee-for-service payment system allows physicians to make up for most of the cuts by providing more services.³¹ And when physicians cannot make up for the cuts, they often choose not to provide services at all in the Medicare and Medicaid programs.³²

C. Cost Containment Through Physician-Hospital Alignment

The ACA addresses the problems with the current fee-for-service system with a number of initiatives aimed at bringing physicians and hospitals together to do what is best for patients at the lowest possible cost. Some of those provisions promote so-called “bundled payments” to physician-hospital groups and shared-savings programs.³³ These programs encourage hospitals and physicians to collaborate to implement electronic medical record systems, create standard-order sets based on evidence about improved outcomes (“evidence based care”), and standardize supply ordering and administrative processes such as operating room schedules so that patients do not need multiple hospital admissions for the same condition.³⁴ They also encourage the use of lower cost providers such as physician assistants wherever possible.³⁵

Many policy makers and industry leaders argue for the kinds of models the ACA encourages. Dr. David Pate, CEO of St. Luke’s Healthcare in Kansas City, Missouri makes the case for physician-hospital alignment this way:

Reimbursement cuts have not worked in the past and are unlikely to work in the future. Instead, a new model is necessary. Providers must take an active role in shaping this new model if they hope to avoid further cuts in reimbursement. The new model must center on payment for value instead of payment for volume of services. It is unlikely that hospitals or physicians can do this alone. In a new era of hospital-physician relationships, we can fix what is wrong with health care—we can make it safer, high

31. See generally CONG. BUDGET OFFICE, KEY ISSUES IN ANALYZING MAJOR HEALTH INSURANCE PROPOSALS 99–116 (Dec. 2008), available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/99xx/doc9924/12-18-keyissues.pdf>.

32. Karen DeBolt, *What Will Happen to Granny? Ageism in America: Allocation of Healthcare to the Elderly & Reform Through Alternative Avenues*, 47 CAL. W. L. REV. 127, 155–56 (2010).

33. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, sec 3001(a), §§ 1899, 1945, 3022, 10335, 124 Stat. 129, 395, 396, 940 (codified as amended at 42 U.S.C. § 1395jjj).

34. *Id.* sec. 3022, §§ 1899, 10307, 124 Stat. at 940 (2013).

35. *Id.*

reliability, reduce unnecessary services, reduce and eliminate irrational variation, tear down silos and reduce fragmentation, make care more convenient and provide it in lower cost settings, make care more patient-centered, make care more effective, engage patients in their care, and ultimately make health care more affordable.³⁶

One of the most innovative and potentially significant of the ACA's strategies is to encourage the formation of ACOs.³⁷ In an ACO, physicians and hospitals jointly assume responsibility for care delivery to, and financial outcomes of, a particular group of patients.³⁸ The physicians and hospitals earn annual bonuses if the ACO meets certain measures of patient health and lowers the cost of care delivery. The Final Rule implementing ACOs predicts that the ACOs established by the ACA's Medicare Shared Savings Program could result in net savings to CMS of \$470 million during the period 2012–2015.³⁹

In October 2011, CMS released the ACO Final Rule, which significantly modified the requirements for ACOs.⁴⁰ The changes gave ACO participants greater flexibility in eligibility, governance, and operations.⁴¹ In conjunction with the Final Rule, CMS created a new type of ACO, the Advance Payment ACO Model, to enable small ACOs to get payments for start-up and infrastructure costs.⁴²

A related alignment strategy in the ACA is the Patient-Centered Medical Home (PCMH). A PCMH is an interdisciplinary group of providers led by a primary care provider intended to provide high-quality, cost effective and coordinated care for patients.⁴³ PCMHs are similar to

36. Pate, *supra* note 10, at 13.

37. Patient Protection and Affordable Care Act, sec. 3022, §§ 1899, 10307 (2013) (codified as amended at 42 U.S.C. § 1395jii).

38. Diane R. Rittenhouse, *Primary Care and Accountable Care—Two Essential Elements of Delivery-System Reform*, 361 NEW ENG. J. MED. 2301, 2301–02 (Dec. 10, 2009), available at <http://www.nejm.org/doi/pdf/10.1056/NEJMp0909327>.

39. Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67,962, 67,963, tbl. 8 (Nov. 2, 2011) (codified at 42 C.F.R. pt. 425); 76 Fed. Reg. 19,640 (proposed Apr. 7, 2011); see also MEDICARE, *supra* note 13, at 7 (“[S]hared savings programs, if implemented on a broad scale, could lower hospital costs sufficiently to reduce Medicare’s hospital payments.”).

40. 76 Fed. Reg. 67,802, 67,804 (Nov. 2, 2011) (codified at 42 C.F.R. pt. 425).

41. *Id.*

42. Medicare Program; Advanced Payment Model, 76 Fed. Reg. 68,012, 68,012 (issued Nov. 2, 2011).

43. AM. HEALTH LAWYERS ASS’N, THE ACO HANDBOOK: A GUIDE TO ACCOUNTABLE CARE ORGANIZATIONS 29–30 (Peter A. Pavarini et al. eds., 1st ed. 2012) (discussing the applied medical home as a recipe for reform).

ACOs, with the largest difference between ACOs and PCMHs being that an ACO consolidates multiple levels of care while a PCMH is a single primary care practice.⁴⁴

The PCMH concept was first introduced by the American Academy of Pediatrics in 1967 as a way to provide coordinated care for children with special needs.⁴⁵ The model has evolved since its initial creation to include allowing physicians to share in savings from “reduced hospitalizations associated with physician-guided care management in the office setting. . . [and] additional payments for achieving measurable and continuous quality improvements” in addition to the regular fee-for-service payment for face-to-face patient visits.⁴⁶

Over 100 PCMH demonstration projects have been conducted and thirty-one states are planning or creating PCMH pilots as the popularity of the concept grows.⁴⁷ The ACA included a program to provide \$25 million in funding to support primary care PCMHs.⁴⁸ Another provision created an option for states to provide coordinated care in the Medicaid program for persons with two or more chronic conditions or designated risk factors.⁴⁹ Because of the proven financial savings from PCMHs, the health care industry is experimenting with ways to expand it.⁵⁰ For example, hospitals are beginning to use the PCMH model to coordinate and manage small and

44. David L. Longworth, *Accountable Care Organizations, the Patient-Centered Medical Home, and Health Care Reform: What Does It All Mean?*, 78 CLEV. CLINIC J. MED. 571, 577 (Sept. 2011), available at <http://www.ccjm.org/content/78/9/571.full.pdf+html>; see also AM. HOSP. ASS'N, PATIENT-CENTERED MEDICAL HOME: AHA RESEARCH SYNTHESIS REPORT 10 (Sept. 2010), available at <http://www.aha.org/research/cor/patient-centered/index.shtml> (discussing characteristics and statistics related to PCMHs).

45. Elliott S. Fisher, *Building a Medical Neighborhood for the Medical Home*, 359 NEW ENG. J. MED. 1202 (2008), available at <http://www.nejm.org/doi/full/10.1056/NEJMp0806233>.

46. AM. ACAD. OF FAMILY PHYSICIANS, AM. ACAD. OF PEDIATRICS, AM. COLL. OF PHYSICIANS & AM. OSTEOPATHIC ASS'N, JOINT PRINCIPLES OF THE PATIENT-CENTERED MEDICAL HOME 3 (Mar. 2007), available at http://www.aafp.org/dam/AAFP/documents/practice_management/pcmh/initiatives/PCMHJoint.pdf.

47. Amanda Cassidy, *Patient-Centered Medical Homes: A New Way to Deliver Primary Care May be More Affordable and Improve Quality, but How Widely Adopted Will the New Model Be?*, HEALTH AFF., Sept. 14, 2010, at 3, available at www.healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_25.pdf.

48. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3502, 124 stat. 129, 512-14; 42 U.S.C. § 256a-1 (2012).

49. 42 U.S.C. § 1396w-4 (Supp. IV 2006).

50. Press Release, Blue Cross Blue Shield, Blue Cross Blue Shield of Michigan Saves an Estimated \$155 Million Over Three Years From Patient-Centered Medical Home Program (July 8, 2013), available at <http://www.bcbsm.com/content/microsites/blue-cross-blue-shield-of-michigan-news/en/index/news-releases/2013/july-2013/bcbsm-saves-155-million-pcmh.html>.

medium-sized practices with employed physicians.⁵¹ It also seems likely that the model will be a part of ACOs in some form.⁵²

D. Cost Containment through Increased Fraud and Abuse Enforcement

In the congressional debate on the ACA, proponents of the Bill touted fraud recovery as an important source of funding to counterbalance the costs of extending insurance coverage to millions of new people.⁵³ “[T]he National Health Care Anti-Fraud Association, an organization of . . . private insurers and public agencies, estimates that some \$60 billion (about 3% of total annual health care spending) is lost to fraud every year.”⁵⁴ During fiscal year 2011, “the Federal government won or negotiated approximately \$2.4 billion in health care fraud judgments and settlements, and it attained additional administrative [settlements or penalties].”⁵⁵

The ACA attempted to raise that number even higher. It increased the budget of the Health Care Fraud and Abuse Control Program by \$10 million per year for 2011–2019.⁵⁶ Additionally, it increased funding for the HHS Office of Inspector General (OIG), FBI, and Medicare Integrity Program by the rate of increase in the Consumer Price Index over the previous year for 2011–2019,⁵⁷ resulting in an additional \$350 million for consolidated-governmental-anti-fraud efforts for fiscal years 2011 through 2020.⁵⁸

51. See generally AM. HOSP. ASS’N, *supra* note 44 (discussing the role hospitals could play in the PCMH model under the ACA).

52. CATHERINE T. DUNLAY ET AL., GETTING ORGANIZED TO PROVIDE ACCOUNTABLE CARE: PHYSICIAN AND HOSPITAL PERSPECTIVES IN STRUCTURING AN ACO 2 (2010), available at http://www.healthlawyers.org/Events/Programs/Materials/Documents/PHYHHS11/dunlay_etal_including_examples_1-2.pdf.

53. John K. Iglehart, *Finding Money for Health Care Reform—Rooting Out Waste, Fraud, and Abuse*, 361 NEW ENG. J. MED. 229, 229–31 (2009), available at <http://www.nejm.org/doi/pdf/10.1056/NEJMp0904854> (discussing governmental efforts to strengthen antifraud measures to increase recoupment of improper payments).

54. John K. Iglehart, *The Supercharged Federal Effort to Crack Down on Fraud and Abuse*, 29 HEALTH AFF. 1093, 1093 (2010), available at <http://content.healthaffairs.org/content/29/6/1093.full.pdf+html>.

55. DEP’T OF HEALTH & HUMAN SERV’S. & DEP’T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FISCAL YEAR 2011, at 1 (2012), available at <https://oig.hhs.gov/publications/docs/hcfac/hcfacreport2011.pdf>.

56. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402(i), 124 stat. 129, 761 (2010) (codified as amended at 42 U.S.C. § 1395(i)(k)).

57. *Id.*

58. Press Release, U.S. Dep’t of Justice, Office of Pub. Affairs, Departments of Justice and Health and Human Services Team Up to Crack Down on Health Care Fraud (Nov. 5, 2010), available at www.justice.gov/opa/pr/2010/November/10-ag-1256.html.

The ACA also bolstered the fraud and abuse laws in several important ways to decrease the burden on prosecutors enforcing the law.⁵⁹ The law revised the “public disclosure” provisions in the FCA to greatly increase the sources of public information that can be used as a basis for a *qui tam* action⁶⁰ and altered the rules regarding what is classified as an “original source” of information for a *qui tam* action.⁶¹ It also changed the Federal Sentencing Guidelines to increase offense levels by 20–50% for health care crimes involving more than \$1 million.⁶²

II. THE CLASH BETWEEN FRAUD AND ABUSE LAWS AND PHYSICIAN ALIGNMENT STRATEGIES

A. Overview of Fraud and Abuse Laws

While a number of statutes can be used to combat health care fraud, four statutes in particular are used most often: the Anti-Kickback Statute (AKS), the Physician Self-Referral Law (known in the health care industry as the “Stark Law” after its author, former congressman Pete Stark), the Civil Monetary Penalties Law (CMP) and the False Claims Act (FCA).⁶³ These laws were written for a system in which physicians are generally at arm’s length from hospitals rather than part of a coordinated system.⁶⁴ They are intended to prevent physicians and hospitals from billing the government for unnecessary or duplicative services or products.⁶⁵ They are also intended to prevent patient care from being compromised by physician self-referrals if the physician chose a test or product for its profit potential rather than what was best for the patient.⁶⁶

59. See 31 U.S.C. § 3730(h)(3) (2012) (placing a three-year statute of limitations on bringing a claim).

60. *Id.* § 3730(e)(4)(A).

61. *Id.* § 3730(e)(4)(B).

62. 18 U.S.C. § 24(a) (2006).

63. See Health Care Fraud Prevention and Enforcement Action Team (HEAT), Office of Inspector General (OIG), *Federal Health Care Fraud and Abuse Laws*, DEP’T OF HEALTH AND HUMAN SERVS., <http://oig.hhs.gov/compliance/provider-compliance/training/files/HandoutLegalCitations508.pdf> (last visited Dec. 1, 2013) (listing health care fraud and abuse laws); see also JENNIFER STAMAN, CONG. RESEARCH SERV., RS22743, HEALTH CARE FRAUD AND ABUSE LAWS AFFECTING MEDICARE AND MEDICAID: AN OVERVIEW 1–3 (2010), available at <http://www.aging.senate.gov/crs/medicaid20.pdf> (providing an overview of the Federal Anti-Kickback Statute, the Stark Law, and the Federal False Claims Act).

64. See STAMAN, *supra* note 63, at 3, 6.

65. 31 U.S.C. § 3729(a)(1)(B) (Supp. IV 2006).

66. See Limitation on Certain Physician Referrals, 42 U.S.C. § 1395nn(a)(1) (2006) (prohibiting physicians from referring patients to a hospital or other healthcare provider if that physician

1. The Anti-Kickback Statute

The Federal AKS prohibits offering, paying, soliciting, or receiving any remuneration in return for referring patients or purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering of any good, facility, item, or service paid for by a federally funded health care program.⁶⁷ The AKS requires intent: the Government must show that the illegal payments were made “knowingly and willfully.”⁶⁸ The law’s purpose is to limit the potential for money to influence health care providers’ patient-care decisions.

Prior to the enactment of the ACA, the federal circuits had interpreted the intent requirement in several different ways.⁶⁹ To resolve these conflicting interpretations, the ACA mandated that “a person need not have actual knowledge of [the AKS] or specific intent” to be found guilty.⁷⁰

2. The Physician Self-Referral Law

In 1989, Representative Pete Stark became concerned about what he saw as the failure of the AKS to curb physician self-referrals and the abuse of the Medicare system wrought by those self-referrals.⁷¹ He was particularly troubled by joint ventures between physicians and other providers.⁷² His concern was sparked by a 1989 HHS OIG report,⁷³ which found that patients of physicians with some type of self-referral interest in the patient’s care were receiving 45% more lab services than Medicare patients generally.⁷⁴ That differential in services costs Medicare an estimated \$28 million per year.⁷⁵

In response to the OIG report, Representative Stark proposed the Ethics in Patient Referrals Act of 1988, commonly referred to as the “Stark Law,”

or a family member of that physician stands to profit from investment in that hospital or healthcare provider).

67. 42 U.S.C. § 1320a-7b(b) (2011).

68. 42 U.S.C. § 1320a-7b(b)(1) (2011).

69. *See, e.g., Hanlester Network v. Shalala*, 51 F.3d 1390, 1396–97 (9th Cir. 1995) (referencing differences between definitions of intent between the Ninth Circuit and Tenth Circuit).

70. 42 U.S.C. § 1320a-7b(h) (2011).

71. Irvin “Ham” Wagner, *The Difficulty of Doing Business with Stark in an Ever-Changing and Overly Complex Regulatory Environment: After Twenty Years, Where are We Heading?*, 19 ANNALS HEALTH L. 241, 243–44 (2010).

72. *Id.*

73. OFFICE OF INSPECTOR GEN., DEP’T OF HEALTH & HUMANS SERVS., FINANCIAL ARRANGEMENTS BETWEEN PHYSICIANS AND HEALTH CARE BUSINESSES, OAI 12-88-01410, at iii (May 1989), available at <https://oig.hhs.gov/oei/reports/oi-12-88-01410.pdf>.

74. *Id.*

75. *Id.*

or simply “Stark,” in honor of its author.⁷⁶ The Law prohibits referrals by physicians to an entity in which the physician or an immediate family member has a financial relationship for a “designated health service” for which payment may be made under Medicare, unless an exception applies.⁷⁷

The term “financial relationship” is defined very broadly. It includes ownership and any type of compensation arrangement.⁷⁸ “Designated health services” include lab, radiology, inpatient, and outpatient-hospital services, among other things.⁷⁹ The Stark Law prohibits any entity from billing government-payment programs such as Medicare, for services provided pursuant to a noncompliant referral during the “period of disallowance.”⁸⁰

Some of the common practices and arrangements that implicate Stark are referrals within a group practice, medical-director agreements, and physician part-time employment or independent-contractor agreements.⁸¹ Other situations in which Stark issues arise are physician investments in hospitals, and arrangements between physicians and other designated health-service providers such as clinical laboratories, diagnostic-imaging centers, physical therapy companies, durable medical equipment companies, and lease agreements for space or equipment.⁸² Other types of agreements that raise Stark issues are hospital-physician recruitment agreements, marketing agreements with entities owned by physician or hospital investors that do not reflect fair market value for necessary

76. Limitation on Certain Physician Referrals, 42 U.S.C. § 1395nn (2006). The Stark Law and supporting regulations have been modified significantly over the years to add or expand covered designated health services and exceptions. This Article refers to the laws and regulations collectively as “Stark” or “the Stark Law” unless otherwise noted.

77. 42 U.S.C. § 1395nn(a)(2)(B) (2006).

78. 42 U.S.C. § 1395nn(a)(2) (2006); 42 C.F.R. § 411.354(a) (2012).

79. 42 U.S.C. § 1395nn(h)(6) (2006); 42 C.F.R. § 411.351 (2012).

80. 42 C.F.R. § 411.353(c) (2012). This period is defined as

starting on the date the financial relationship is first noncompliant and lasting until *no later than* (1) the date on which the financial relationship satisfies an exception; (2) the date on which all excess compensation is returned to the party that paid it; or (3) the date on which all additional required compensation is paid to the party to which it is owed.

Lesley Reynolds & Ben Koplin, *Overpayment Liability and Self-Disclosure Under the New CMS Protocol*, J. HEALTH CARE COMPLIANCE, May–June 2011, at 23, 24. Because the regulation used “no later than,” rather than “the latter of,” the regulation could be seen as extending the period of disallowance “beyond the date the financial relationship is technically cured to the date on which any excess compensation is finally returned or money due is finally paid.” *Id.*

81. 42 U.S.C. §§ 1395nn(b), (e)(2), (e)(4) (2006); 42 C.F.R. §§ 411.355, 411.357(c), (g), (h) (2012).

82. 42 U.S.C. §§ 1395nn(e)(1), (8) (2006); 42 C.F.R. §§ 411.357(a), (b), (i), (k), (l), (p) (2012).

services, and practice compensation programs that reward shareholders or employee-physicians based on orders of designated health-services.⁸³

The reason that these practices and arrangements often pass muster is that the Stark Law contains numerous exceptions covering the most common types of financial relationships between hospitals and physicians.⁸⁴ For example, exceptions are made for fair market value compensation, employment agreements, personal-services arrangements, and office-space rental.⁸⁵ There are also numerous exceptions applicable to physicians practicing in groups,⁸⁶ as well as an exception for services personally performed by a physician.⁸⁷

Each of these exceptions has very specific requirements, and failure to meet those requirements will result in a Stark violation.⁸⁸ For example, the employment exception requires a written agreement for a term of at least one year that both parties signed.⁸⁹ The agreement must set out the compensation formula, which cannot change during the term of the agreement.⁹⁰ The compensation must be at fair market value, and may not be determined in a manner that takes into account the volume or value of referrals generated by the physician.⁹¹

The Stark Law is extremely detailed and does not require the element of intent to trigger legal liability.⁹² The lack of an intent requirement, coupled with the complexity of the Law, has caused the Stark Law to be criticized, almost since its passage, as inflexible and excessively punitive.⁹³ It is quite easy for health care providers to unwittingly run afoul of the Law, leaving them liable to repay fees earned for patient care, in addition to civil penalties.⁹⁴

83. 42 U.S.C. §§ 1395nn(e)(3)(B), (e)(5) (2006); 42 C.F.R. §§ 411.357(e), (i), (k), (l), (p) (2012).

84. 42 U.S.C. § 1395nn(e) (2006); 42 C.F.R. § 411.357(e)(i)(k)(l)(p) (2012).

85. 42 U.S.C. § 1395nn(e) (2006); 42 C.F.R. § 411.357 (2012).

86. 42 U.S.C. § 1395nn(b) (2006); 42 C.F.R. § 411.355 (2012).

87. 42 U.S.C. § 1395nn(e)(3)(A) (2006); 42 C.F.R. § 411.357(d) (2012).

88. 42 U.S.C. § 1395nn(a)(1) (2006).

89. 42 U.S.C. § 1395nn(e)(2) (2006); 42 C.F.R. § 411.357(c) (2012).

90. 42 U.S.C. § 1395nn(e)(3)(A)(v) (2006).

91. *Id.*

92. See Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, LAW & PSYCHOL. REV. 1, 24 (2003) (noting that the Stark law is a strict liability law).

93. See *id.* at 22–24 (citing commentators' descriptions of Stark as "confusing, complicated, over-reaching, too complex and intrusive, antiquated," among many others (internal quotation marks omitted)).

94. Richard Lower & Robert D. Stone, *Off with Their Heads! Summary Execution for Technical Stark Violations – and a Proposal to Commute the Sentence*, 3 J. HEALTH & LIFE SCI. L. 112, 147 (Apr. 2010) (discussing the strict liability nature of Stark violations despite no intent and no harm

Furthermore, the Stark Law can be a moving target. Numerous amendments and HHS regulatory changes have only made the Stark Law more difficult for health care providers to interpret and follow.⁹⁵ The American Hospital Association recently described the Stark Law as “increasingly complex, confusing and continually changing.”⁹⁶ One commentator recently summed up his complaints about the Stark Law this way:

The difficulty of doing business with Stark these past two decades should serve as a warning with respect to current and future attempts at healthcare reform. Unnecessarily complex and overly restrictive regulatory intervention does not adapt well to evolving technologies, nor does it lead to efficiencies in the marketplace.⁹⁷

3. The False Claims Act

The False Claims Act (FCA) is not limited to health care, but it has been employed in almost all of the very large recoveries by the Government in the health care industry.⁹⁸ The FCA imposes liability on any person or entity who knowingly (1) presents or causes to be presented to an officer or employee of the federal government a false or fraudulent claim paid or approved by the government; or (2) makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the government.⁹⁹ Penalties can be up to triple the “amount of damages which the government sustains because of the act of that person.”¹⁰⁰

brought to patients or the public); *see also* Reynolds & Koplin, *supra* note 80, at 24 (showing no intent requirement under Stark).

95. AM. HEALTH LAWYERS ASS'N, A PUBLIC POLICY DISCUSSION: TAKING THE MEASURE OF THE STARK LAW 5, 6 (2009) [hereinafter AM. HEALTH LAWYERS ASS'N], available at <http://www.healthlawyers.org/hlresources/PI/ConvenerSessions/Documents/Stark%20White%20Paper.pdf>.

96. Letter from Rick Pollack, Exec. Vice President, Am. Hosp. Ass'n, to Kathleen Sebelius, Sec'y, Dep't of Health & Human Servs. 1 (July 16, 2010) [hereinafter AHA Letter], available at <http://www.aha.org/aha/letter/2010/100716-cl-ppaca.pdf>.

97. Wagner, *supra* note 71, at 247.

98. Press Release, U.S. of Justice, Office of Pub. Affairs, Justice Department Recovers Nearly \$5 Billion in False Claims Act Cases in Fiscal Year 2012 (Dec. 12, 2012), available at <http://www.justice.gov/opa/pr/2012/December/12-ag-1439.html>.

99. 31 U.S.C. § 3729(a)(1)–(2) (Supp. IV 2011).

100. 31 U.S.C. § 3729(a)(1)(G) (Supp. IV 2011).

The ACA codified a position long taken by the government that a violation of either the AKS or Stark creates a *per se* violation of the FCA.¹⁰¹ Because of the enormous potential penalties under the FCA, any alignment strategy that implicates the AKS or Stark statutes exposes a physician or hospital to tremendous, even “ruinous” liability.¹⁰²

While the government can, and certainly does, bring FCA actions on its own initiative, much FCA enforcement in health care is achieved using the *qui tam* provisions.¹⁰³ These provisions allow *qui tam* relators, or “whistleblowers,” to file an FCA action under seal for up to two years, during which time the government can investigate the claim and decide whether it wants to “intervene” and take over the action.¹⁰⁴ The relator may then receive up to one-third of the proceeds of an action or the settlement of the claim.¹⁰⁵ These provisions give potential relators every incentive to pursue claims, while removing any prosecutorial discretion that might otherwise mitigate against pursuing marginal claims.¹⁰⁶

4. Civil Monetary Penalties

The Civil Monetary Penalties Law (CMP) includes two provisions relevant to physicians and hospitals entering into arrangements designed to award efficiency and eliminate waste. The so-called “program integrity laws” are designed to prevent payment arrangements that might encourage providers not to give patients the care that they need.¹⁰⁷ One section prohibits hospital payments to physicians to reduce or limit services (the “gainsharing CMP”),¹⁰⁸ while another prohibits beneficiary inducements.¹⁰⁹

101. 42 U.S.C. § 1320a-7a (Supp. V 2006).

102. Ankur J. Goel & Daniel H. Melvin, *New CMS Self-Disclosure Protocol Fundamentally Changes the Landscape For Stark Law Compliance and Enforcement*, 14 HEALTH CARE FRAUD REP. 862 (2010), available at http://www.mwe.com/info/pubs/BNA_Goel_Melvin.pdf.

103. DAVID E. MATYAS, ET AL., *LEGAL ISSUES IN HEALTHCARE FRAUD AND ABUSE: NAVIGATING THE UNCERTAINTIES* 225 (4th ed. 2012).

104. 31 U.S.C. § 3730(c) (2006).

105. 31 U.S.C. § 3730(d) (2006).

106. See Joan H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 203 (2001) (discussing concerns that prosecutorial discretion is undermined when the Department of Justice is forced to allocate significant resources to reviewing numerous *qui tam* filings); cf. Dayna Bowen Matthew, *The Moral Hazard Problem with Privatization of Public Enforcement: The Case of Pharmaceutical Fraud*, 40 U. MICH. J. L. REFORM 281, 297–98 (2007) (recognizing prosecutorial discretion is minimized by *qui tam* filings, though the government may have an economic incentive to allow them to proceed to litigation).

107. 42 U.S.C. § 1320a-7a(a)(1)(A), (B), (E) (2006).

108. 42 U.S.C. § 1320a-7a(b)(1), (2) (2006).

109. 42 U.S.C. § 1320a-7a(a)(5) (2006).

The CMP Statute does not contain exceptions and does not authorize any government agency to establish exceptions by regulation. Also, these statutes generally do not distinguish between necessary and unnecessary care.¹¹⁰ The one place in which a distinction is made is the section allowing Medicare-managed care organizations, called “Medicare Advantage Plans,” to use financial incentives to limit unnecessary care.¹¹¹

B. How Alignment Strategies Implicate Fraud and Abuse Laws

1. Alignment as an Overall Strategy

The fraud and abuse laws are largely a response to the vulnerabilities inherent in a fee-for-service health care environment.¹¹² In a “pay for performance” system, in which providers are paid for delivering high-quality, effective care rather than for the quantity of services, laws that were necessary under a fee-for-service regime may be unnecessary at best, and fatal to the new approach at worst. Health care providers and their attorneys are struggling to fit new strategies into the old regulatory framework, making issues around hospital-physician alignment among the most important health-law issues for 2013.¹¹³

In response to requests from some members of the Senate, the GAO recently studied some of the ways in which the fraud and abuse laws act as a roadblock to such reform.¹¹⁴ The Agency interviewed officials from HHS, the OIG, CMS, and the Department of Justice (DOJ) responsible for writing and enforcing health care fraud and abuse laws.¹¹⁵ They also interviewed legal and health care policy experts, representatives from five health care industry groups, and officials from ten health care systems.¹¹⁶

110. Publication of the OIG Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, 64 Fed. Reg. 37,985–01, 37,985 (July 14, 1999).

111. 42 U.S.C. § 1395mm(i)(8) (2006); *see also* MEDICARE, *supra* note 13, at 24 (explaining the rationale behind the managed-care-organization exception to the CMP).

112. A number of writers have made this observation, but Julie E. Kass and John S. Linehan make it the basis of their proposal discussed in detail in Part IV.A.3. Kass & Linehan, *supra* note 15, at 79.

113. *See* Peyton M. Sturges et al., *Health Reform Drives Medicaid, Medicare, Fraud and Abuse to Top Ranks for 2013*, 22 HEALTH L. REP. 39 (Jan. 10, 2013), available at <http://www.wilentz.com/uploaddata/articlesandpublicationsfiles/health-reform-drives-medicare-fraud-and-abuse-to-top-ranks-for-2013.pdf>.

114. *See* MEDICARE, *supra* note 13, at 3–4 (identifying the fraud and abuse laws and describing the study of those laws).

115. *Id.* at 4–5.

116. *Id.* at 5.

The GAO concluded in GAO Report 12-355 (Report) that important aspects of the fraud and abuse laws must change to accommodate reform, but stopped short of calling for any specific changes.¹¹⁷ The Report concluded that, “[GAO’s] work suggests that stakeholders’ concerns may hinder implementation of financial incentive programs to improve quality and efficiency on a broad scale.”¹¹⁸

The specific issues highlighted in the Report are discussed below. This section identifies the specific ways the laws hinder implementation of pay-for-performance. Later sections will pick up where the GAO left off and recommend changes to the existing laws.

2. ACOs, PCMHs, and Other Payment-Bundling Strategies

Because ACOs, PCMHs, and other payment-bundling strategies involve financial relationships between physicians and the hospitals to which they refer, these arrangements raise the same types of AKS, Stark, and CMP issues as other physician-hospital contracts. “Payment bundling” refers to making a single predetermined payment to cover all goods and services furnished to a government health care program beneficiary for a single episode of care.¹¹⁹

While there are limited waivers available for some ACOs, these waivers do not exist for PCMHs or other bundling strategies that fall short of the ACO in the extent of integration.¹²⁰ Commentators on the interim waivers argued for wider protection, yet CMS was not willing to expand them.¹²¹ So, despite fifty years of experience with the PCMH model, providers interested in using this model must comply with all the existing fraud and abuse laws.

3. Gainsharing and Other Financial Incentive Programs

In the 1990s, hospitals began to recognize the need to provide incentives to physicians to assist them in controlling costs.¹²² Many hospitals developed “gainsharing” programs to pay physicians to

117. *See id.* at 36–37 (discussing the challenges of implementing financial incentive laws within the current legal framework).

118. *Id.* at 37.

119. Bundled Payments for Care Improvement Initiative: Request for Application, 76 Fed. Reg. 53,137, 53,138 (Aug. 25, 2011).

120. Kass & Linehan, *supra* note 15, at 121.

121. *Id.* at 111.

122. Gail R. Wilensky et al., *Gain Sharing: A Good Concept Getting a Bad Name?*, 26 HEALTH AFF. 58, 59–61 (2006).

standardize procedures in operating rooms or with ordering supplies or to control hospital-acquired infections.¹²³ It was not long, however, before the OIG announced that these gainsharing programs ran afoul of the CMP provisions concerning payments to limit care.¹²⁴ HHS eventually issued proposed regulations to solve the problem, but later announced that it would not proceed to finalize the regulatory changes.¹²⁵

The OIG has been willing to issue advisory opinions approving some gainsharing arrangements on a case-by-case basis. Since 2001, the OIG has issued fourteen such opinions.¹²⁶ While these opinions provide helpful guidance, this approach does not give the industry the certainty necessary to proceed with crafting incentive arrangements on a large scale.¹²⁷ Furthermore, the OIG only has authority to address the AKS and the CMP laws. It cannot address the Stark Law.¹²⁸ CMS has not issued any advisory opinions on gainsharing and the Stark Law.¹²⁹

One example will suffice to show how all of these regulatory uncertainties work together to create obstacles for hospitals seeking to use incentive payments to align physicians with their quality goals. Suppose General Hospital (Hospital) wants to pay physicians to assist in creating strategies to lower readmissions after discharge for pneumonia patients. Patient readmissions sometimes, if not often, reflect failure of the system to appropriately care for the patient the first time around.¹³⁰ Decreasing readmissions should be good for the patient as well as save the government

123. *Id.* at 60.

124. Publication of the OIG Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, 64 Fed. Reg. 37,985 (July 14, 1999).

125. Exclusions from Medicare and Limitations on Medicare Payment, 73 Fed. Reg. 38,604, 38,606 (July 7, 2008).

126. *See, e.g.*, HHS OIG Advisory Op. No. 01-01 (Jan. 11, 2001); HHS OIG Advisory Op. No. 05-01 (Jan. 28, 2005); HHS OIG Advisory Op. No. 05-02 (Feb. 10, 2005); HHS OIG Advisory Op. No. 05-03 (Feb. 10, 2005); HHS OIG Advisory Op. No. 05-04 (Feb. 10, 2005); HHS OIG Advisory Op. No. 05-05 (Feb. 18, 2005); HHS OIG Advisory Op. No. 05-06 (Feb. 18, 2005); HHS OIG Advisory Op. No. 06-22 (Nov. 9, 2006); HHS OIG Advisory Op. No. 07-21 (Dec. 28, 2007); HHS OIG Advisory Op. No. 07-22 (Dec. 28, 2007); HHS OIG Advisory Op. No. 08-09 (July 31, 2008); HHS OIG Advisory Op. No. 08-15 (Oct. 6, 2008); HHS OIG Advisory Op. No. 08-21 (Nov. 25, 2009); HHS OIG Advisory Op. No. 09-06 (June 23, 2009).

127. The Report stated that, “some legal experts we spoke with told us that although there have not been any FCA cases or settlements, the threat of being the first case has created a chilling effect for providers. Some legal experts told us that as a result, their clients were conservative when implementing such programs.” MEDICARE, *supra* note 13, at 23.

128. *Id.* at 28.

129. *Id.*

130. *See* GAWANDE, *supra* note 13, at 36, 38, 40 (mentioning instances when doctor fallibility leads to patients being discharged before they are ready).

a great deal of money.¹³¹ So, let us assume that the Hospital plans to pay physicians a reasonable hourly fee for their service on a committee developing treatment protocols for pneumonia. The Hospital also wants to track patients admitted for pneumonia and provide an annual bonus to physicians with low rates of readmission.

If the proposal is not intended to induce referrals by physicians to the Hospital and the compensation is at fair market value and not tied to the volume or value of referrals, the plan will survive scrutiny under the AKS. It will not, however, pass muster under the Stark Law. The payment by the Hospital creates a “financial relationship” for Stark purposes. The arrangement cannot meet the Stark exception for fair market value compensation because the payment would be tied to the “volume or value of referrals” to the Hospital. If the agreement fails to meet any of the requirements of either the AKS or Stark, then every procedure the physician performs at the hospital results in a false claim, opening the physician and the Hospital up to triple damages. It will also fail under the CMP law prohibiting any incentives to limit care, even though the intent is only to encourage providers to do everything possible to keep patients healthy and help them avoid having to come back to the Hospital.

The possibility of violating fraud and abuse laws—even, or especially, unintentionally in the case of the Stark Law—and the enormous financial consequences of a violation combine to make providers wary of crafting incentive programs for their physicians. Even though the OIG did not undertake any Stark Law or AKS enforcement actions on the basis of pay-for-performance or gainsharing arrangements between 2005 and 2010, the Report says that “the threat of being the first case has created a chilling effect for providers.”¹³²

The Report went on to say:

There are no exceptions and safe harbors specifically for financial incentive programs, and the Stark law’s “no risk” requirement for new exceptions, makes it difficult for CMS to craft an exception that allows for innovative, effective programs while ensuring that the Medicare program and patients face no risk from abuses.¹³³

131. See RESEARCH TRIANGLE INST., *supra* note 11, at 123 (mentioning reduction in readmissions as a benefit to patients and a source of cost savings).

132. MEDICARE, *supra* note 13, at 23.

133. *Id.* at 36.

Add to the uncertainty of outcome the certainty of significant cost and delay from seeking an advisory opinion, and the result is that “health systems are more likely to implement only those programs that mirror already approved programs or none at all.”¹³⁴

III. HEALTH CARE PROVIDERS’ ATTEMPTS TO THREAD THE NEEDLE

A. *The Employment Model*

1. Why Employment Is the Most Often Used Model

Health-law practitioners’ most often used response to the difficulties of navigating fraud and abuse laws when crafting a physician alignment strategy is to make the physicians employees.¹³⁵ As one writer has said:

The uncertainties and market forces driving hospitals and physicians to consider stronger affiliation and/or integration options also contribute to the sense of urgency. Exploring options such as ACO’s, JV’s [joint ventures], and gain sharing programs to align incentives takes time. The immediacy of the current forces are [sic] driving the most prevalent form of integration seen in the market today which is physician employment by hospitals and health systems.¹³⁶

Physicians themselves have a number of reasons to want to become employees, including the difficulty in complying with regulatory and legislative limitations generally.¹³⁷ Some of these reasons include the prospect of declines in practice revenue in the future along with demands for large investments in electronic medical records and other information technology improvements.¹³⁸ More than half of practicing physicians are now employed by hospitals or health systems.¹³⁹ One health care recruiting

134. *Id.* at 37.

135. *See id.* at 19–22 (describing how hospitals use the Stark Law’s bona fide employment exception to implement financial incentive programs).

136. RANDOLPH GORDON ET AL., DELOITTE, PHYSICIAN/HOSPITAL ALIGNMENT: EMPLOYMENT AGREEMENTS IN THE REFORM ERA (2011), available at http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/us_chs_PhysicianHospitalAlignment_Brochure_061511.pdf.

137. Peggy Naas, *Why Physicians are Seeking Employment*, HOSPS. & HEALTH NETWORKS, (Sept. 20, 2010), http://www.hhnmag.com/hhnmag/jsp/articledisplay.jsp?dcrpath=HHNMAG/Article/data/09SEP2010/092010HHN_Weekly_Naas&domain=HHNMAG.

138. Sturges et al., *supra* note 113, at 22.

139. Robert Kocher & Nikhil R. Sahni, *Hospitals’ Race to Employ Physicians – The Logic Behind a Money-Losing Proposition*, 364 NEW ENG. J. MED. 1790, 1790 (May 12, 2011), available at <http://www.nejm.org/doi/pdf/10.1056/NEJMp1101959>.

company predicts that hospitals could employ as many as 75% of physicians within two years.¹⁴⁰

Employment is appealing from a legal perspective because it offers more leeway under the fraud and abuse laws.¹⁴¹ Both the AKS and Stark Law have specific exceptions for employment.¹⁴² As long as an employment contract complies with the requirements of both of those exceptions, hospitals can pay incentives to the physician-employees that they could not pay to physicians who have their own private practice.¹⁴³

2. Difficulties in the Employment Model

The employment model presents a number of legal and practical challenges. One commentator has said that, “[i]n the healthcare industry today, the only ‘proven’ model for achieving a successful, clinically integrated healthcare delivery system is the physician employment model, an approach that is neither achievable nor desirable for the vast majority of community health care systems in the country.”¹⁴⁴ Sometimes, practitioners experience some difficulty in drafting employment agreements due to somewhat different definitions in the AKS and the Stark Law.¹⁴⁵ The terms “fair market value” and “commercially reasonable” vary between the two statutes and are not clearly spelled out in each law’s accompanying regulations.¹⁴⁶ These differences can make it difficult for compensation consultants to provide good benchmarks to assist hospitals and physicians in creating incentive payments that are certain to pass muster under both exceptions.

Both statutes require that hospitals pay doctors commercially reasonable rates regardless of the money hospitals will make from providing services to referred patients.¹⁴⁷ While the intent of this limitation

140. Alexander et al., *supra* note 23.

141. See generally ROBERT G. HOMCHICK, TOP 10 LESSONS LEARNED FROM THE PHYSICIAN PRACTICE ACQUISITION WARS: STARK AND ANTI-KICKBACK ISSUES IN PHYSICIAN COMPENSATION (2010), available at http://www.dwt.com/files/Publication/13b8e0b2-f48f-45dd-9390-21bf043070a0/Presentation/PublicationAttachment/441d2c0e-c6b9-4e91-8a2e-224d286b7b8c/publication_news_06-10_Homchick_Top10Lessons.pdf (detailing the rules and exceptions for physicians to receive compensation under the Stark Law).

142. 42 U.S.C. § 1320a-7b(b)(3) (2006); 42 C.F.R. § 1001.952 (2012).

143. *Id.*

144. Robin Locke Nagele, *Hospital-Physician Relationships After National Health Reform: Moving from Competition to Collaboration*, PENN. BAR ASS’N Q., Jan. 2011, at 11.

145. KIM H. ROEDER & KENNETH R. SCHWARTZ, AM. HEALTH LAWYERS ASS’N, COMPLIANCE ISSUES IN PHYSICIAN EMPLOYMENT RELATIONSHIPS 1 (2009).

146. 42 C.F.R. §§ 411.357(c), 1001.952(i) (2012).

147. *Id.*

is clearly to prevent disguised payments for kickbacks, it does create a challenge.¹⁴⁸ In what other industry would the employer not be allowed to compensate an employee for personally contributing to the bottom line by referring customers? The policy arguments behind the AKS aside, the practical effect of this limitation is to prevent the physician and hospital from completely aligning their incentives if they are relying on the employment exceptions for the AKS and the Stark Law.

In addition to the problems of qualifying every alignment arrangement under the slightly varying standards of the two statutes, there is a larger problem of convincing all physicians to make the jump to employment in the first place. Employment simply does not appeal to all physicians.¹⁴⁹ As of 2008, physicians owned close to half of all physician practices.¹⁵⁰ To some extent, the physicians most comfortable with employment have already made or are planning to make the move to employment. This situation leaves those for whom employment has no appeal without a viable means to collaborate with hospitals under the current fraud and abuse regime.

The Report described one urban health-system in the southwestern part of the country that had implemented a financial incentive program for their employed physicians to reward them for meeting clinical quality measures, such as diabetes-glucose measures, pediatric immunizations, and patient satisfaction measures.¹⁵¹ However, the program was necessarily very limited in its impact because less than ten percent of the hospital's physicians are employees.¹⁵²

Recent FCA settlements have also caused health care providers and practitioners to question whether employment agreements really are the safe option they may have previously assumed.¹⁵³ One practitioner recently noted:

[S]imply structuring an arrangement as an employment relationship no longer ends the analysis Other investigations and settlements have involved situations in which the party had obtained a fair market valuation. Again, the message here is that the existence of the valuation is not as important as the manner in which the valuation was conducted The bottom line is that

148. See MEDICARE, *supra* note 13, at 21 (explaining the challenges of the fair market value requirement).

149. Kocher & Sahni, *supra* note 139, at 1792.

150. *Id.* at 1791 fig. 1.

151. MEDICARE, *supra* note 13, at 19–20.

152. *Id.* at 20.

153. *Id.* at 23.

DOJ and the relator bar are taking on issues and arrangements that might not have drawn a provider's attention in the past.¹⁵⁴

B. Other Types of Financial-Incentive Arrangements

1. The Stark Law Hurdles

When employment models do not cover a sufficiently large percentage of physicians, many hospitals turn to financial-incentive models that can work for independent physicians, such as the Stark fair market value compensation arrangement or the Stark exception for physician incentives in health plans.¹⁵⁵ According to the Report, providers view these arrangements as more difficult to create and less certain to satisfy regulatory requirements than employment agreements.¹⁵⁶ This is particularly true when comparing salaried employees to physicians receiving incentive payments.¹⁵⁷

A major problem with any financial-incentive model is establishing the fair market value of the compensation.¹⁵⁸ It is easier to meet the fair market value requirement of AKS and the Stark Law with salary arrangements because there are a number of publicly available surveys of wages.¹⁵⁹ However, attempting to value a physician's services under a unique incentive program is much more difficult.¹⁶⁰

Also, the Stark exceptions on which providers' counsel rely to craft incentive programs require that compensation not reflect the volume or value of referrals made by the physician to the hospital.¹⁶¹ Therefore, the programs must be structured to distribute payments to all participating physicians regardless of a particular physician's level of effort. The Report notes that, "[a]s a result, according to some of the legal experts we spoke with, an underperforming physician would not have an incentive to change his or her practices to improve the quality of care."¹⁶²

154. Sturges et al., *supra* note 113, at 5 (quotations omitted) (quoting Sanford V. Teplitzky).

155. See MEDICARE, *supra* note 13, at 20 (describing one health system's use of the Stark exception for independent physicians).

156. *Id.* at 21.

157. *Id.*

158. *Id.*

159. *Id.*

160. *Id.*

161. 42 U.S.C. § 1395nn(e)(2)(B)(ii) (2006).

162. MEDICARE, *supra* note 13, at 21.

2. The CMP Law Issues

In order to comply with the CMP provisions on limitation of care, hospitals' incentive-compensation plans may use a fixed-fee arrangement that does not compensate physicians for reducing or limiting services.¹⁶³ One example provided in the Report is a program in which a hospital might pay a physician to complete his or her rounds by a specific time.¹⁶⁴ The program might result in patients being discharged earlier than would otherwise occur, but the payments would not be tied to that result.¹⁶⁵

The Report states:

Some legal experts we spoke with . . . consider the CMP law a major hurdle to the development and implementation of financial incentive programs that allow the hospital to reward physicians for lowering hospital costs and improving quality by reducing medically unnecessary services. . . . Another industry group stakeholder, in a May 2008 statement, asserted that the CMP law has dissuaded providers from pursuing financial incentive programs using specific practice protocols, even those based on clinical evidence and recognized as best practices, because of provider concern that OIG might find that the program provided an incentive to reduce or limit services.¹⁶⁶

C. Limiting Incentive Arrangements to Patients Covered By Private Payers

Since the fraud and abuse laws apply only to care paid for by governmental programs, it should theoretically be possible to create programs to reward physician alignment that only include revenue from private payers. However, the Report indicates that providers have a hard time separating commercial-pay patients from Medicare patients.¹⁶⁷ As a result, the providers end up structuring their programs to comply with Medicare even though they are not required to in order to protect themselves from inadvertent fraud and abuse issues if a Medicare patient is accidentally included in the incentive program.¹⁶⁸

163. *Id.* at 24.

164. *Id.* at 25.

165. *Id.*

166. *Id.* at 25–26.

167. *Id.* at 22.

168. *Id.*

D. Advisory Opinions

CMS and the OIG advisory opinion processes are available, but they are limited in scope and expensive.¹⁶⁹ The Report noted that expenses for seeking an advisory opinion ranged from \$15,000 to \$50,000, depending on the complexity of the issues.¹⁷⁰ Furthermore, they can take up to a year to receive.¹⁷¹ CMS will not provide advisory opinions on fair market value,¹⁷² often the key issue in structuring an incentive program. Although an advisory opinion offers certainty, it does not offer any additional regulatory flexibility.

E. Waivers

When the ACO Final Rule came out in late 2011, making operational changes to provide the ACO Medicare Shared Savings Program (MSSP) model with more flexibility and creating the Advance Payment Model ACO for smaller providers, many hospitals and physician groups began exploring forming an ACO.¹⁷³ To encourage ACO formation, the government offered waivers of the applicability of the Stark Law.¹⁷⁴ These waivers, however, were limited to ACOs in the MSSP program.

As one author has noted, “notwithstanding these operational adjustments [in the MSSP final waiver rule], the most consequential factor in promoting the MSSP’s success will be the government’s use of its waiver authorities with respect to the fraud and abuse laws.”¹⁷⁵ Several commenters on the CMS’s proposed regulations on fraud and abuse waivers for ACOs had expressed concern that the proposed waiver design was too limited to promote many innovative ACO arrangements.¹⁷⁶

The final waiver rule included five specific waivers covering: (1) the start-up period for an ACO; (2) the ACO’s participation in the MSSP period and for a specified time after; (3) shared savings distributions; (4) the AKS and the gainsharing CMP for ACO arrangements that meet an existing Stark exception; and (5) a patient-incentive waiver of the CMP beneficiary-

169. *Id.* at 12, 30–31.

170. *Id.* at 30.

171. *Id.* at 31.

172. 42 C.F.R. § 411.370(c) (2007).

173. Final Waivers in Connection with the Shared Savings Program, 76 Fed. Reg. 67,992, 68,007 (Nov. 2, 2011).

174. *Id.* at 67,993.

175. Kass & Linehan, *supra* note 15, at 108.

176. *Id.* at 109.

inducements provision for medically related incentives that encourage preventive care.¹⁷⁷

It is important to note that the final waiver rule does not waive compliance with the Stark Law, but merely says:

[The] waiver is intended to ease the compliance burden on providers that might elect to use existing Physician Self-Referral Law exceptions for their ACO arrangements and to reassure those with existing arrangements that already fit in such an exception that they need not undertake a separate legal review under the Federal anti-kickback statute or Gainsharing CMP.¹⁷⁸

F. Demonstration Projects

The ACA included a provision requiring HHS to establish a national pilot-program on payment bundling for the many projects that fall short of the high degree of integration required for an ACO.¹⁷⁹ While some demonstration project recommendations are outlined in the legislation,¹⁸⁰ HHS also has general authority to develop or demonstrate improved methods for the investigation and prosecution of fraud in federal health care programs.¹⁸¹

Demonstrations involving PCMHs include models for high-need patients, women's health care, and those that move primary care practices away from fee-for-service based reimbursement and toward comprehensive payment or salary-based payment.¹⁸² In addition, a number of states were selected to participate in demonstration projects in which practices can receive traditional Medicare fee-for-service reimbursement as well as additional compensation for the transformation of primary care practices into PCMHs.¹⁸³

177. 76 Fed. Reg. 67,992, 68,006 (Nov. 2, 2011). Because the waivers relate to several legal authorities and to allow for subsequent modification, the waivers were not codified in the Code of Federal Regulations but they may be found on the CMS and OIG websites.

178. *Id.*

179. *Id.*

180. 42 U.S.C. § 1395b-1(a)(1)(A) (2006); 42 U.S.C. § 1315a(b) (2006) (recommending twenty project models, including the promotion of broad payment and practice reform in primary care, and provision of payment to providers for using patient decision-support tools that improve individual understanding of medical treatment options).

181. 42 U.S.C. § 1395b-1(a)(1)(J) (2006).

182. 42 U.S.C. § 1315(2)(B) (Supp. V 2006).

183. *Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS., http://www.cms.gov/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf (last updated April 5, 2012).

The ACA authorizes waiver of the fraud and abuse laws for the Centers for Medicare & Medicaid Innovation (CMMI) demonstrations under section 3021 of the ACA, but CMMI has not issued any guidance implementing the waivers.¹⁸⁴ The agency seems to be addressing the fraud and abuse laws as part of the application process for the CMMI program.¹⁸⁵ For example, CMMI's Bundled Payments for Care Improvement Initiative (BPCII) lays out requirements for gainsharing arrangements.¹⁸⁶ CMS created BPCII in August 2011.¹⁸⁷

Health care providers have welcomed these new models that encourage participation by providers of many types and sizes.¹⁸⁸ The bundled payment model is similar to that of the PCMH and ACO, but it is focused on an individual patient, and so is seen as less risky for providers.¹⁸⁹ CMS has proposed to "consider exercising [its] waiver authority with respect to the fraud and abuse laws . . . as may be necessary to develop and implement" the BPCII.¹⁹⁰ To date, however, CMS has not issued any "concrete assurances in the form of prospective bright line waivers [that] could spur greater confidence and participation."¹⁹¹

IV. A SEARCH FOR SOLUTIONS

A. Regulatory Agency Action

The agencies charged with regulating health care providers, principally CMS and the OIG, could significantly improve the environment for innovation in payment for Medicare and Medicaid by simply using their existing authority to modify the Stark Law and CMP regulations.

184. MARILYN TAVENNER, CTRS. FOR MEDICARE & MEDICAID SERVS., JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES (2013), *available at* <http://www.cms.gov/about-cms/agency-information/performancebudget/downloads/cmsfy13cj-.pdf>.

185. Bundled Payments for Care Improvement Initiative: Request for Applications, 76 Fed. Reg. 53,137, 53,138 (Aug. 25, 2011) (detailing the application process for organizations to participate in the bundled payments initiative).

186. *Id.*

187. *Id.*

188. Kass & Linehan, *supra* note 15, at 118.

189. *Id.*

190. CTR. FOR MEDICARE & MEDICAID INNOVATION, BUNDLED PAYMENTS FOR CARE IMPROVEMENT INITIATIVE (Jan. 4, 2012), *available at* <http://innovation.cms.gov/Files/x/Bundled-Payments-for-Care-Improvement-Frequently-Asked-Questions-document-01-31-2012.pdf>.

191. Cybil G. Roehrenbeck, *Roadblock to Payment & Delivery Reform: The Program Integrity Laws*, 8 ABA HEALTH ESOURCE No. 10 (June 2012), http://www.americanbar.org/newsletter/publications/aba_health_esource_home/aba_health_law_esource_0612_roehrenbeck.html.

1. The Stark Law

The Stark Law includes a provision allowing CMS to create regulatory exceptions for financial relationships that do not pose a risk of patient or program abuse.¹⁹² According to the Report, “CMS has acknowledged that existing Stark law exceptions may not be sufficiently flexible to encourage a wider array of nonabusive and beneficial incentive programs that both promote quality and achieve cost savings.”¹⁹³ However, CMS has said that the Statute’s requirement that exceptions “not pose a risk” makes it very difficult to craft an exception for incentives that can meet the standard.¹⁹⁴ In 2008, the Agency proposed a new exception covering financial-incentive programs,¹⁹⁵ but ultimately took no action to finalize it. CMS officials told the GAO they have no plans to do so.¹⁹⁶

It is noteworthy that HHS took issue with the initial draft of the Report and requested that the final report include a note that HHS believes it has used its waiver authority to allow “many relationships that would have been covered under CMS’s proposed 2008 Stark Law exception.”¹⁹⁷ Regardless of HHS’s views of its largess in using its waiver authority, the GAO concludes its report this way: “We added a footnote addressing this issue but maintain that organizations that do not have programs under either the Medicare Shared Savings Program or Innovation Center are still required to comply with the Stark Law and its existing exceptions, which our stakeholders noted was challenging.”¹⁹⁸

2. The CMP Law

The OIG hinted that it might permit certain payments in the shared-savings model in Advisory Opinion 11-01.¹⁹⁹ The Opinion states that the ACA “amends the [CMP’s] statutory definition of ‘remuneration’ by adding

192. 42 U.S.C. § 1395nn(b)(4) (2006); 42 C.F.R. §§ 411.350-389 (2012).

193. MEDICARE, *supra* note 13, at 18.

194. *Id.*

195. Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009, 73 Fed. Reg. 38,502 (proposed July 7, 2008); Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions, 73 Fed. Reg. 38,604 (proposed July 7, 2008).

196. MEDICARE, *supra* note 13, at 19.

197. *Id.* at 35 n.101. “In its written comments, HHS sought to clarify the Department’s position on CMS’s use of its authorities to permit certain financial incentive programs—using regulatory exceptions and waivers—that the Department did not believe we had clearly described in the draft.” *Id.* at 37.

198. *Id.* at 38.

199. HHS OIG Advisory Op. No. 11-01 (Jan. 3, 2011), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-01.pdf>.

a new exception . . . for ‘any other remuneration which promotes access to care and poses a low risk of harm to patients and federal health care programs.’”²⁰⁰ At this time, no regulations relating to this provision have been promulgated.

3. Expansion of Opportunities for Waivers

Julie Kass, a well-known health care practitioner, argues that the government has now recognized that health care providers are not going to move in large numbers to innovative reform models “until more sweeping regulatory changes are made.”²⁰¹ She argues that the federal government could do a great deal to encourage alignment initiatives by doing three things: (1) preempt state laws to ensure alignment with the ACO; (2) create a fast track for advisory opinions for the MSSP; and (3) extend waiver treatment to other CMMI-sponsored demonstration programs and to Pioneer model ACOs.²⁰² Ms. Kass also argues that HHS should create an “enforcement gradient,” which she defines as “a clear line of separation between traditional [fee-for-service] based delivery modalities and collaborative arrangements.”²⁰³ She states:

The ACO-related waivers provide a beachhead of regulatory protection for providers seeking to undertake innovative delivery reform. In time, the government may expand special regulatory treatment to cover a wider array of delivery system initiatives, such as Pioneer ACOs, PCMHs, and bundled payment models. This progression would result in the creation of two independent fraud and abuse enforcement systems—a traditional one that will continue to govern FFS-based arrangements and a new one that will apply to integrated delivery models.²⁰⁴

Perhaps some of the roadblocks to greater alignment can be removed. One method could be to extend the balance between enforcement and flexibility established in the MSSP program with case-by-case waivers for other physician alignment strategies that are not as comprehensive as ACOs.

200. *Id.*

201. Kass & Linehan, *supra* note 15, at 121.

202. *Id.* at 123.

203. *Id.* at 124.

204. *Id.* at 121.

B. A New Exception for ACOs

In addition to agencies loosening regulations to allow for innovative-payment models, some congressional action will also be needed to effectuate alignment. As the health care industry moves haltingly in the direction of replacing the fee-for-service model for pay-for-performance programs, the regulatory environment must move with it.

These changes could be based on what is learned from some of the experiments currently being conducted by the CMS Innovation Center (Center). The Center is using its Pioneer ACO program for private payers to experiment with alternatives to fraud and abuse laws that still protect patient care from the influence of the profit motive.²⁰⁵ The Pioneer model is for organizations moving from a fee-for-service model to a value-based model.²⁰⁶ It includes thirty-two organizations, and features safeguards for program integrity such as beneficiary survey results, provider profiles, and risk scores.²⁰⁷ CMS is testing a number of ways to protect against limitations on necessary care, such as analyzing data on service utilization, and using surveys to assess beneficiaries' reports on the quality of their care.²⁰⁸

Once the results of the CMS experimental programs are in, Congress should consider codifying a new exception under the AKS, the Stark Law, and the CMP Law for ACOs. The MSSP ACOs have inherent safeguards against abuse in the many hurdles required to get CMS approval for a new MSSP ACO.²⁰⁹ Other types of ACOs and other programs such as incentive payments admittedly raise higher levels of risk. However, if the CMMI studies on these other models can lead to a loosening of the current regulatory stranglehold on these innovative ideas, then CMMI will have fulfilled the purpose for which Congress created it.

205. See, e.g., Medicare Program; Pioneer Accountable Care Organization Model: Request for Applications, 76 Fed. Reg. 29,249, 29,250 (May 20, 2011) (outlining the intent and purpose of the Pioneer ACO program); see also Press Release, Ctrs. For Medicare & Medicaid Servs., Affordable Care Act Gives Providers New Options to Better Coordinate Health Care (May 17, 2011), available at <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-Releases/2011-Press-Releases-Items/2011-05-17.html> (describing in more detail the initiatives of the Pioneer ACO program).

206. See Medicare Program; Pioneer Accountable Care Organization Model: Request for Applications, 76 Fed. Reg. 29,249 (May 20, 2011) (describing the new requirements).

207. MEDICARE, *supra* note 13, at 35 (requiring service utilization and other value-based measures).

208. See Medicare Program; Pioneer Accountable Care Organization Model: Request for Applications, 76 Fed. Reg. at 29,250 (May 20, 2011).

209. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3022, 124 Stat. 119, 395-99 (2010) (detailing the many reporting and quality requirements for a MSSP ACO).

C. Repeal or Significant Limitation of the Physician Self-Referral Law

One way to make it easier for physicians and hospitals to align would be to eliminate the Stark Law and rely entirely on the AKS to address truly abusive situations. Representative Stark acknowledged at the time of the Law's passage that the AKS should theoretically have been enough to address the issues covered by his statute.²¹⁰ However, Stark said, "clever deal makers have found a loophole."²¹¹ He went on to say, "Referral schemes are being disguised as legitimate business arrangements, most commonly as partnerships involving referring physicians, but also as consulting or similar arrangements."²¹² The intent of the parties behind such relationships was "quite clear," he said, "to lock in referrals by creating a web of financial relationships binding the referring physicians to the provider."²¹³ Representative Stark also argued that the AKS was not sufficient to prevent these abuses because of the difficulty of proving that a particular arrangement was deliberately structured to induce referrals, and because of the OIG's shortage of investigators and lack of resources to begin investigations.²¹⁴

In the years since the Stark Law's passage, many commentators have criticized the law for its lack of an intent requirement and enormous complexity.²¹⁵ The criticism began almost immediately after its passage²¹⁶ and has gained force with each amendment of the law.²¹⁷ Congress considered some major changes to the Stark Law in 1995, including repeal of the prohibitions based on compensation arrangements and the reduction in the list of services subject to the ban.²¹⁸

For over twenty years since the Stark Law's passage, we have had the opportunity to test Representative Stark's argument that the Law is necessary to fill in gaps left by the AKS and to lessen the burden on prosecutors. Today, many high-dollar AKS settlements attest to the government's ability to go after the truly abusive arrangements on the basis

210. 135 Cong. Rec. H240-01 (daily ed. Feb. 9, 1989) (Statement of Rep. Stark).

211. *Id.*

212. *Id.*

213. *Id.*

214. *Id.*

215. Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 *LAW & PSYCHOL. REV.* 1, 24 (2003).

216. *See id.* at 22-24 (2003) (citing commentators' descriptions of Stark as "confusing," "complicated," "over-reaching, too complex and intrusive," and "antiquated," among many others).

217. AM. HEALTH LAWERS ASS'N, *supra* note 95, at 6.

218. Balanced Budget Act of 1995, H.R. 2491, 104th Cong. (1995) (vetoed by President William Clinton, Dec. 6, 1995).

of the AKS and the FCA alone.²¹⁹ For example, the government used the AKS coupled with the FCA to obtain a \$108 million settlement with Christ Hospital in 2010.²²⁰ In December 2010, the DOJ reached a \$41 million settlement with Kos Pharmaceuticals in another FCA and AKS investigation.²²¹

The argument could be made that in light of the many prosecutions that use both the AKS and FCA, repeal of the Stark Law would not make much of a difference to health care providers. If the same situations always implicate both the Stark Law and the AKS, then how could repeal of the Stark Law free providers to create more hospital-physician alignments? One answer may be that any decrease in the complexity of complying with the fraud and abuse laws is a step in the right direction. If the Stark Law is not necessary to address true abuses, then why not free the health care industry from the need to comply with it?

Another argument in favor of repealing the Stark Law is that, to the extent conduct violates the Stark Law and not the AKS, that conduct is largely inconsequential to the financial integrity of government health care programs. Arrangements that violate the Stark Law without also violating the AKS are often what some practitioners call “technical” violations of Stark.²²² The violations relate to compliance with the specific requirements of various exceptions rather than to more substantive problems.²²³ Kevin McAnaney, Chief of the Health and Human Services Office of the Inspector General’s Industry Guidance Branch from its creation in 1997 until May 2003, has stated that most of the issues under the Stark Law relate to these technical violations rather than anything more substantive.²²⁴

219. Melissa Rifai, *Department of Justice’s Historic FCA and AKS Settlement*, HEALTH REFORM WATCH (Apr. 12, 2013), available at <http://www.healthreformwatch.com/2013/04/04/departement-of-justices-historic-fca-and-aks-settlement/>.

220. Press Release, U.S. Dep’t of Justice, Office of Pub. Affairs, *The Health Alliance of Greater Cincinnati and the Christ Hospital to Pay \$108 Million for Violating Anti-Kickback Statute and Defrauding Medicare and Medicaid* (May 21, 2010), available at www.justice.gov/opa/pr/2010/May/10-civ-602.html.

221. Press Release, U.S. Dep’t of Justice, Office of Pub. Affairs, *Kos Pharmaceuticals to Pay More Than \$41 Million to Resolve Kickback and Off-Label Promotion Allegations* (Dec. 7, 2010), available at www.justice.gov/opa/pr/2010/December/10-civ-1402.html.

222. Jean W. Veilleux, *Catching Flies with Vinegar: A Critique of the Centers for Medicare and Medicaid Self Disclosure Program*, 22 MATRIX 169, 180–81 (2012) (using a fictitious example to explain a technical violation of the Stark Law).

223. *Id.* at 180.

224. *OIG ‘Open Letter’ to Industry Cites Kickbacks in Self-Disclosure Protocol*, 13 HEALTH CARE FRAUD REP. 258 (Apr. 8, 2009); see also AHA Letter, *supra* note 96, at 3 (describing how the Stark Law’s increased complexities make it difficult for compliance by even the best intentioned providers, leaving open the possibility of disproportionately large liability in relation to the conduct giving rise to the violation).

Mr. McAnaney's sentiments were echoed in the American Health Lawyers Association (AHLA) White Paper on the Stark Law, which was based on two Convener Sessions held in April and June 2009.²²⁵ The participants in the sessions included in-house counsel to health care providers, academics, attorneys in firms representing providers, *qui tam* relators under the FCA, and former government attorneys. Attorneys currently serving the government observed but did not participate in the sessions. The AHLA White Paper concluded that "innocent or highly technical violations [of the Stark Law] can result in ruinous liability," and "technical violations that cause no harm to the federal program can trigger huge penalties."²²⁶ The American Hospital Association (AHA) recently described the Stark Law as "increasingly complex, confusing and continually changing."²²⁷ Though the AHA had originally supported the Stark Law, it asked CMS in 2012 to consider changes to "restore fairness" to the law.²²⁸

Even the Law's creator laments ever having passed the law named after him.²²⁹ Now former Representative Stark said on a 2007 Forbes magazine blog that although he believes the Law's purposes were well founded, he now thinks it may have done more harm than good.²³⁰ He said: "It gave every shyster and promoter a loophole," and that he would like to "go back and strip down the original fuzzy language so the law simply forbids kickbacks."²³¹ Perhaps it is now time to do exactly that.

D. Modification of the CMP

If the OIG's position is correct—that the Agency does not have the authority to insert a "medical necessity" limitation on the reach of the CMP prohibitions—Congress will need to step in to correct the Law's overbreadth. As discussed earlier, this issue is the greatest single problem providers cite as a barrier to greater hospital-physician alignment.²³² Unlike the repeal of the Stark Law, this change would not require a major adjustment in the government's approach to program integrity. It would

225. AM. HEALTH LAWYERS ASS'N, *supra* note 95, at 1.

226. *Id.* at 3, 6.

227. AHA Letter, *supra* note 96, at 1.

228. *Id.* at 4.

229. Patrick A. Sutton, *The Stark Law in Retrospect*, 20 ANNALS OF HEALTH L. 15, 16 (2011) (citing David Whelan, *Stark Regrets: I Shouldn't Have Written That Law*, FORBES (Nov. 30, 2007), <http://blogs.forbes.com/sciencebiz/category/bylinemathew-herper/page/18/>).

230. *Id.*

231. *Id.*

232. See *supra* Part III.B.2.

simply tailor the law more closely to its purpose: to prevent providers from shortchanging patients in their care to benefit themselves financially.

CONCLUSION

The ACA encourages physicians and hospitals to work together to improve quality of care and decrease health care costs, focusing in particular on ACOs and incentive payment-plans. Many health policy scholars have argued that any real reform of our health care system that hopes to offer improved quality at a price we can afford must include alignment of incentives between physicians and hospitals. The Institute of Medicine concluded that the U.S. health care system should “[s]tructure payment to reward continuous learning and improvement in the provision of best care at lower cost. Payers should structure payment models, contracting policies, and benefit designs to reward care that is effective and efficient and continuously learns and improves.”²³³

The physician-hospital alignment that is critical to accomplishing these goals often butts up against fraud and abuse statutes intended for a fee-for-service environment. Instead of resolving this conflict, the ACA exacerbates it by strengthening these laws and relying upon increased enforcement of them as part of the strategy to fund the expansion of health care coverage. Congress, CMS, and the OIG must face and resolve these conflicts if the ACA’s promise is to be realized.

233. THE INST. OF MED. REPORT, *supra* note 14, at 245 (emphasis omitted).